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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,377	02/26/2002	Catherine Defrenne	GSKB-109US	4141
26130	7590	04/10/2009	EXAMINER	
RATNER & PRESTIA- SB DIVISION P.O. Box 980 Valley Forge, PA 19482				BASKAR, PADMAVATHI
ART UNIT		PAPER NUMBER		
1645				
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		04/10/2009		PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	09/936,377	DEFRENNE ET AL.
	Examiner	Art Unit
	Padma V. Baskar	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 January 2009.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 25,29,31,32,35,40,41,43,50,51,57,59,60,62-67 and 69-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 25,32,35,40,41,43,60,64 and 67 is/are allowed.
- 6) Claim(s) 29,31,50,51,57,59,62,63,65,66 and 68-72 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/27/09</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Amendment

1. The amendment filed on 1/27/09 is acknowledged and entered.

Status of claims

2. Claims 25, 29, 31-32, 35, 40-41, 43, 50-51, 57, and 59-60, 62-67, and 69-72 are pending.

Claims 1-24, 26, 28, 30, 33-34, 36-39, 42, 44-49, 52-56, 58, 61 and 68 are canceled .

Claims 29, 31 and 71-72 have been amended.

Information Disclosure Statement

3. The Information Disclosure Statement filed on 1/27/09 has been reviewed and a signed copy of the same is attached to this action.

Claim objection moot

4. In view of cancelation of claim 61, the objection is moot.

Claim Rejections - 35 USC 112, first paragraph maintained

5. The rejection of claims 29, 31, 50-51, 57, 59, 62-63 , 65-66 and 68-72 under 35 U.S.C. 112, first paragraph is maintained for the same reasons as set forth in the previous office action.

Applicant 12/19/08 argues that the examiner refers to variants and applicant claims call for fragments and not variants. Applicant states that the specification recites the sequence SEQ.ID.NO:2 as well as any fragments of contiguous amino acids within it. Applicant also states fragments such as lacking an N-terminal leader sequence, a transmembrane domain (page 5), or a C-terminal anchor domain, alpha-helix and alpha-helix forming regions, beta-sheet and beta-sheet-forming regions (page 10) etc have been disclosed with function. Therefore, the specification provides the precise structure of the BASB082 polypeptide fragments and both structural and functional descriptions of exemplary fragments.

Applicants arguments are fully considered but has not been found persuasive because first the examiner would like to bring applicant's attention to page 10 which refers that fragments include, for example, truncation polypeptides having a portion of an amino acid sequence of SEQ ID NO:2,4,6,8,10 or of variants thereof, such as a continuous series of residues that includes an amino- and/or carboxyl-

Art Unit: 1645

terminal amino acid sequence. Therefore, referring fragments as variants is correct . The examiner reviewed the suggested pages and found that the fragment (if necessary when coupled to a carrier) is capable of raising an immune response which recognizes the BASB082 polypeptide. However, the specification fails to provide such correlation. Additionally there are many fragments within SEQ.ID.NO:2. Therefore, a genus which embraces widely variant species cannot be achieved by disclosing only one species (SEQ.ID.NO:2) within the genus and the specification provides no correlation between claimed fragments and function of said fragment. Further ,the art as discussed in the previous office action indicates that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody. Therefore, the rejection is maintained.

6. The rejection of claims 29, 31, 50-51, 57, 59, 62-63 , 65-66 and 68-72 under 35 U.S.C. 112, first paragraph is maintained for the same reasons as set forth in the previous office action.

Applicant 12/19/08 argues that one of ordinary skill would be able to prepare not only SEQ ID NO: 2, but any of its immunogenic fragments of at least 15 /20 or more contiguous amino acids and refers to specification ,pages 47, line 5, 11, page 49, line 20, page 61, line 12 to page 74, line 19, page 10, line 22, to page 12, line 11, page 59, lines 15 -16, pages 55, 59, 61, 62, 66-74 for support and guidance Applicant states that making fragments and screening them were within the capability of the skilled artisan. Even if the quantity of experimentation might be extensive, it is all routine, and therefore cannot be non-enabling and refers to *Ex parte Kubin*, 83 U.S.P.Q.2d 1410, 1415-16 (Bd. Pat. App. & Int. 20070

Applicants arguments are fully considered but has not been found persuasive because the examiner reviewed the suggested pages, and found no support for a composition comprising an immunogenic fragments of 15/20 contiguous amino acids of SEQ.ID.NO:2 as claimed. One of ordinary skill may be able to prepare fragments from a full length protein but using those fragments in a composition against *N.meningitidis* requires more experimentation because the specification fails to disclose which 15/20 contiguous amino acids would be able to produce antibodies and recognize which 15/20 contiguous fragment with in SEQ.ID.NO:2 that can be used to detect or diagnose infections caused by various strains/serotypes *N.meningitidis* . Neither the specification nor the *N.meningitidis* art teach fragments of SEQ.ID.NO:2 can be successfully used. With reference to Kubin et al, the comparison is not correct because the present invention is directed to *N.meningitidis* polypeptide and is well known in the art that *N.meningitidis* infections are strain and serotype specific and therefore, using claimed polypeptide fragments for all *N.meningitidis* infections is not routine. Hence, the claimed fragments are not enabled.

Art Unit: 1645

Remarks

7. Claims 25, 32, 35, 40-41, 43, 60, 64 and 67 are allowable.

Claims 29, 31, 50-51, 57, 59, 62-63 , 65-66 and 68-72 are rejected.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action

9. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 156, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571) 272-0956.

Respectfully,

/Padma V Baskar/

Examiner, Art Unit 1645

/Robert B Mondesi/

Supervisory Patent Examiner, Art Unit 1645